REMARKS

Claims 1-7 and 10-19 are pending. Applicants have cancelled claim 2, added new claims 20 and 21, and amended claims 1, 10 and 13, along with various other claims. Upon entry of this Amendment, claims 1, 3-7 and 10-21 will be pending and under examination.

35 U.S.C. §112, second paragraph

The Examiner rejected claims 10 and 13 as failing to comply with the requirements of 35 U.S.C. §112, second paragraph. In response, applicants have amended claims 10 and 13 and added new claims 20 and 21 to address the language objected to.

35 U.S.C. §102

The Examiner also rejected claim 1 as allegedly anticipated by EP 439430 ("'430"). According to the Examiner, '430 teaches a transdermal system having a top layer, ACE inhibitor layer, adhesive layer and protective layer, and that the ACE inhibitors are present as monosalts such as libenzapril monomaleate.

In response, but without conceding the correctness of the Examiner's rejection, applicants note that amended claim 1 recites an enumerated list of ACE inhibitors which do not encompass the compounds taught in '430.

Notwithstanding the above, applicants further note that page 5 of '430 mentions benazeprilate dilithium salt and benazeprilate dipotassium salt, i.e. disalts of benazeprilate which make clear that the ending ate defines a dicarboxylic acid whereas the ending pril without ate defines a monoester. Thus, it is apparent that libenzapril monomaleate is a monomaleate of a monoester of libenzaprilate, i.e. a dicarboxylic acid. Claim 1, however, recites a mono-salt of a dicarboxylic acid, wherein the mono-salt is obtainable with an acid.

35 U.S.C. §103

The Examiner rejected claims 1-7 and 10-19 under 35 U.S.C. §103 as allegedly obvious over U.S. Patent No. 6,303,141 ("'141 patent") in view of EP '430.

In response, applicants respectfully traverse.

The '141 patent, according to the Examiner, teaches a transdermal delivery device comprising, in relevant part, an ACE inhibitor and Eutanol G as a permeation enhancer. As the Examiner concedes, the '141 patent does not teach the monosalts recited in claim 1. Likewise, EP '430 does not teach such monosalts either. Thus, the cited references combined fail to teach the elements of the claimed invention.

Moreover, applicants note that the invention unexpectedly solves the problem of obtaining ACE inhibitors which (i) remain stable with respect to decomposition in a transdermal system and (ii) exhibit outstanding skin permeation. See, e.g., the specification at page 2, lines 25-29, which states that "Decomposition of the ACE inhibitor in the matrix occurs to such a great extent that, even after a short period of storage, the content of decomposition products is so high that the tolerance limit for degradation products is far

exceeded. In addition, it is not possible, using non-stabilised ACE inhibitors, to achieve adequate permeation through skin *in vivo*." This unexpected solution lies in the form of the inhibitors set forth in claim 1 in the form of dicarboxylic acids derivatized to form diesters and mono salts formed with acids.

In support of applicants' position, applicants submit a copy of a Declaration dated May 29, 2007 and signed by Joerg Nink of Hexal AG. The Declaration sets forth experimental evidence regarding the stability of two ACE inhibitors and the skin permeation of one of the inhibitors.

Applicants maintain that the cited references fail to create a reasonable expectation of success regarding the unexpected properties of the claimed system.

Applicants further make the following observations. Interpretating the term "salt" as used in the '141 patent (column 1, line 58 and column 2, line 28) as a term "which reads on monosalts" is not tenable since it not only encompasses mono-salts and di-salts obtainable with acids but also mono-salts and di-salts obtainable with bases. Di-salts obtainable with bases do not appear in claim 1.

For the above reasons, applicants maintain that the claimed inventions is not obvious.

If any additional fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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